REMARKS

Claims 1, 6 and 12 have been amended to clarify the claim language. Claim 1 has been amended to further define the inactivating/heating step, support for which is found, for example, on page 3, lines 22-25, page 6, lines 12-14 of the present application. Further, the test composition is now defined as comprising a test microorganism, for example, as described on page 4, lines 20-28, of the present application. Finally, claim 1 has been amended to clarify that the test composition is suitable for "being used in a method for determining the presence or absence of microbial growth." Claim 6 has been amended to include appropriate antecedent basis for "composition." Claim 12 has been amended to delete the reference to "natural." No new matter has been added.

The Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1, 6 and 12 have been rejected as allegedly indefinite. This rejection is traversed. Nonetheless, claim 1 has been amended to define the test composition as one that is suitable for being used in a method for determining the presence or absence of an antimicrobial residue. Further, claims 6 and 12 have been amended to overcome the alleged lack of antecedent basis. Accordingly, it is believed this basis for rejection may be withdrawn.

The Rejections Under 35 U.S.C. § 102

The rejection of claims 1, 2, 4, 6, and 12 under 35 U.S.C. § 102(b) as being anticipated by Charm (U.S. Patent 5,354,663) is traversed and reconsideration is respectfully requested. The arguments made in the response filed April 14, 2005, are incorporated herein as they are still applicable.

The facts of the present case are on point with *Perricone v. Medicis Pharm. Corp.*, 2005 U.S. App. LEXIS 28061 (hereinafter "*Perricone*") decided December 20, 2005, the date the Office action was mailed. A copy of this case is enclosed herewith.

In *Perricone*, the Federal Circuit reversed the District Court's determination that the cited art anticipates particular claims of the issued patent. The claims in question are directed to "a method for treating skin sunburn" comprising topically applying to the skin sunburn "a lotion." The prior art taught application of the lotion to skin. The Federal Circuit stated that issue was *not* whether the prior art lotion, if applied to skin sunburn would inherently treat that damage but whether the prior art discloses the application of its composition to skin sunburn. The District Court improperly assumed what the prior art did not disclose or render inherent. Please see *Perricone,* paragraphs 10 and 11 under the heading "Anticipation." In its analysis, the Federal Circuit found that skin sunburn is not analogous to skin surfaces generally, and that the prior art was silent about any sunburn prevention or treatment benefits and the mechanisms underlying such uses.

Similarly, the issue in the present case should *not* be whether the prior art heating step, if applied to a sample and test would inherently inactivate compounds, but rather whether the cited references disclose inactivating compounds in a sample and test. Much like the prior art in *Perricone* was silent with respect to applying the lotion to skin sunburn, the cited references here are silent with regard to the step of inactivating any natural disturbing compounds present in the contacted sample *and test*. Further, the cited references are silent about any benefits of performing the activation on a sample and test and also are silent regarding mechanisms underlying performing the inactivating step on *both* the sample *and test*. Like the District Court in *Perricone*, the Examiner improperly assumed what the prior art did not disclose or render inherent. If skin sunburn is not analogous to skin generally, then likewise inactivating any natural disturbing compounds present in the sample and test is not analogous to heating or incubating generally. Even a stronger case can be made that inactivating performed on the sample and test is not analogous to any of a) inactivating a sample only, b) heating a sample and test where the sample alone was previously inactivated, and/or c) incubating a sample and test with no reference to the mechanisms relating to the inactivating step. These issues are discussed in more detail below. Much like in *Perricone*, where the Federal Circuit reversed the finding of anticipation, the anticipation rejection over Charm should be withdrawn in the present application.

Further, Applicants respectfully submit that the Office has mischaracterized Charm. The Office alleges that Charm discloses inactivating "at least some" of the natural disturbing compounds and discloses "a second inactivating step" which are not disclosed or suggested therein. More specifically, the Office first alleges that Charm discloses a time and temperature sufficient to destroy "at least some" of the inhibitors of the sample. Please see page 4, lines 3-4 of the action. Applicants respectfully submit that Charm does not disclose destroying "at least some of" the natural inhibitors in the sample in column 3, lines 32-39, as alleged in the action. Rather, Charm states that the sample is heated "to a temperature sufficiently high to destroy the natural *inhibitors* in the sample, and thereby enhancing the further sensitivity of the test... (emphasis added)." There is no mention in Charm that only "some of" the natural inhibitors are destroyed. Thus, Charm does not disclose or suggest that any natural inhibitors remain after the heating step. As such, Charm does not disclose or suggest the claimed step of inactivating any natural disturbing compound present, which mandatorily requires inactivating to be performed on the *sample and test*. In contrast, the inactivating step in Charm is performed on the *sample only*.

Second, on page 4 of the action, the Office alleges that "Applicants have not shown that the absence of a second inactivating step produces a different result." As a preliminary matter, Charm does not disclose a "second inactivating step." Rather, the Office appears to have mischaracterized Charm's spore-shocking heating step as "a second inactivating step." Charm does not disclose, suggest or recognize that inactivating necessarily occurs in the spore-shocking heating step. Thus, as a preliminary matter, it is not clear why applicants would have to make such a showing.

Nonetheless, Example 2 indeed shows that absence of a step that performs inactivation on the sample only, *i.e.*, without the test, gave false positive results caused by the inhibiting effect of natural inhibiting compounds present in the sample. Thus, the Office's allegation that such a showing was not made is not understood. Clarification is respectfully requested.

Rejection of claims 1-6 and 12 under 35 U.S.C. § 102(b) as being anticipated by Inglis is traversed and reconsideration is respectfully requested. The Office action alleges that the "samples

and test organisms (spores) are heated to 85°C for 15 minutes and then subsequently added to agar plates" to determine whether spore growth was inhibited. However, like Charm, Inglis does not disclose heating a sample and test composition comprising a test microorganism. Rather Inglis discloses a centrifuged assay solution (derived from a raw egg mixture) which is heated to 85°C without spores, and which is then added to petri dishes which contain spores. The petri dishes were inoculated with the spores, but the petri dishes were not heated with the spores to 85°C. There is no disclosure that the sample *and test* are heated to 85°C, in contrast to the present claims. Applicants respectfully request the Office to identify such alleged disclosure, if present. Otherwise, applicants respectfully submit that anticipation has not been established, and this rejection may be properly withdrawn.

The rejection of claims 1-6 and 12-13 as allegedly anticipated under 35 U.S.C. § 102(b) over Katz is traversed and reconsideration is requested. The Office alleges that the "samples and test organism (spores) are heated to 85 degrees for 15 minutes," but no such disclosure was found. Rather, Katz describes heating a standard or an egg mixture to 80-85°C and thereafter adding the centrifuged standard or mixture to petri dishes inoculated with the spores, which petri dishes are not heated to 80-85°C. Applicants respectfully request the Office to identify the alleged disclosure, if present. Otherwise, as described above with respect to Inglis and Charm, the steps of the present invention are not disclosed.

Applicants traverse the rejection of claims 1–6 and 12–13 under 35 U.S.C. § 102(b) based on public use or sale of the invention. Applicants respectfully submit that the trade name "Premi®Test" is used for a range of products. The Premi®Test directed to meat and milk tests were on the market and the patent application refers to the them in the background section. In contrast, the Premi®Test egg test protocol was disclosed after the filing date of the present application. A copy of the first leaflet is attached herewith having a printing date of February 2000, which is after the priority date of the present application. The Office alleges that the Geijp reference refers to the egg procedure, however, this abstract clearly refers to the meat test as is apparent from the title, and thus is not relevant to the finding of novelty or obviousness of the present invention. Also, enclosed

herewith is a product insert for the Premi®Test for meat, which was released prior to the filing date of the present application.

The Rejections Under 35 U.S.C. § 103

Applicants traverse the rejection of claims 1-6 and 12-13 as allegedly obvious over Charm. The arguments above with regard to the anticipation rejection over Charm are incorporated herein. The Office alleges that Charm discloses "*samples* need to be heated to a temperature sufficiently high to destroy the natural inhibitors in the sample" (emphasis added). The Office has not shown that Charm discloses that the sample *and test organism* are so heated. Charm shows heat shocking spores in the sample but such *heat shocking* is not a result-effective variable that may be optimized to arrive at the claimed *inactivating* step in accordance with MPEP § 2144.05(II)(B). The result caused by such heat-shocking step is heat shocking and thus, at best, it is a closer argument as to whether a skilled artisan would optimize heat shocking temperatures of Charm's sample and test organism. Nowhere in Charm are inactivating temperatures of a sample and test disclosed and thus, such temperatures cannot be said to be merely optimized.

Moreover, applicants respectfully submit that a skilled artisan would not have applied Charm's method to an egg sample. A skilled person would understand that an egg sample coagulates upon heating and thus would have concluded that further extraction of the anti-microbial residues from the coagulated egg sample was needed. In contrast, the presently claimed invention obviates the extracting method such that the coagulated sample can directly be applied in the tests as if it were a liquid. Applicants have discussed this problem in the art on page 2, paragraphs 2-3, of the present application. Thus, applicants respectfully submit that a skilled artisan would not be led to the claimed process using egg samples, using the disclosure of Charm. Applicants respectfully submit that the omission of a step but the retention of its function, is an indicum of unobviousness. Please see MPEP § 2144.04(II)(A).

Thus, this rejection may be properly withdrawn.

The Rejections Under 35 U.S.C. § 112, first paragraph

Applicants traverse the rejection of claim 12 under 35 U.S.C. § 112, first paragraph (new matter). Claim 12 has been amended to delete the reference to "natural." (Claim 1 has been further amended to define such compounds.) Thus, this rejection may be properly withdrawn.

Applicants traverse the rejection of claims 1-6 and 12-13 as not enabled. Applicants have amended such claims to clarify that the antimicrobial residues are not inactivated. Thus, this rejection may be properly withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 246152016800. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: March 20, 2006

Respectfully submitted,

By Brenda J. Wallack Reg. # 45,193
for Carolyn A. Favorito
Registration No.: 39,183
MORRISON & FOERSTER LLP
12531 High Bluff Drive
Suite 100
San Diego, California 92130-2040
(858) 720-5195

LEXSEE 2005 US APP LEXIS 28061

NICHOLAS V. PERRICONE, M.D., Plaintiff-Appellant, v. MEDICIS PHARMACEUTICAL CORPORATION, Defendant-Cross Appellant.

05-1022, 05-1023

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

432 F.3d 1368; 2005 U.S. App. LEXIS 28061

December 20, 2005, Decided

PRIOR HISTORY: [*1] Appealed from: United States District Court for the District of Connecticut. Judge Christopher F. Droney. Perricone v. Medicis Pharm. Corp., 267 F. Supp. 2d 229, 2003 U.S. Dist. LEXIS 10230 (D. Conn., 2003)

COUNSEL: Raphael V. Lupo, McDermott Will & Emery, of Washington, DC, argued for plaintiff-appellant. With him on the brief were Charles R. Work, Mark G. Davis and David A. Spenard. Of counsel were Mary C. Chapin and Evan Parke.

William J. McNichol, Jr., Reed Smith LLP, of Philadelphia, Pennsylvania, argued for defendant-cross appellant. With him on the brief were Tracy Zurzolo Frisch, Maryellen Feehery and Heather A. Ritch. Of counsel was Charles L. Becker.

JUDGES: Before RADER, BRYSON, and LINN, Circuit Judges. Opinion for the court filed by Circuit Judge RADER. Concurring in part and dissenting in part opinion filed by Circuit Judge BRYSON.

OPINIONBY: RADER

OPINION: RADER, Circuit Judge.

On summary judgment, the United States District Court for the District of Connecticut, No. 3:99-CV-01820, determined that all of the asserted claims of Dr. Nicholas V. Perricone's U.S. Patent Nos. 5,409,693 (the '693 patent) and 5,574,063 (the '063 patent) are invalid and, as to the '693 patent, not infringed. Perricone v. Medicis Pharm. Corp., 267 F. Supp. 2d 229 (D. Conn. 2003). [*2] Dr. Perricone seeks reversal of those judgments while Medicis Pharmaceutical Corporation cross-appeals the district court's refusal to declare the case exceptional under 35 U.S.C. § 285 and to award Medicis its attorney fees. Because the district court erred in its anticipation analysis with respect to claims 1-4 and 7 of the '693 patent, this court reverses and remands the judgments on those claims of the '693 patent. This court otherwise affirms the trial court's decisions of anticipation based on inherency for the remaining claims of the '693 and '063 patents and its double-patenting analysis with respect to claims 9, 11-13, 16, 18, and 19 of the '063 patent. Finally, this court affirms the district court's denial of Medicis' motion under § 285.

I.

Dr. Perricone's patents claim methods of treating or preventing sunburns (the '693 patent) and methods of treating skin damage or disorders (the '063 patent). The '693 patent issued in 1995, tracing priority back to a filing in 1989. The '063 patent issued in 1996, with priority back to the application that resulted in the '693 patent. The information added in that continuation-in-part application does not affect [*3] this case. Thus, both patents disclose essentially the same subject matter: treatment or prevention of various forms of skin damage through the topical application of ascorbic acid (Vitamin C) in a fat soluble form. See '693 patent, col. 2, ll. 26-34; '063 patent, col. 2, ll. 30-36. Specifically, the patents disclose the topical application of ascorbyl fatty acid ester (e.g., ascorbyl palmitate, ascorbyl laurate, ascorbyl myristate, ascorbyl stearate) with a dermatologically acceptable carrier. See '693 patent, col. 2, ll. 26-34; '063 patent, col. 2, ll. 30-36. Because the carrier, as well as the ascorbyl fatty acid ester, is fat soluble, it can "effectively penetrate skin layers and deliver the active ascorbyl fatty acid ester to the lipid-rich layers of the skin." '693 patent, col. 4, ll. 4-6; '063 patent, col. 4, ll. 10-12. Upon reaching the lipid-rich layers of skin, the ascorbyl fatty acid ester produces a number of beneficial effects ranging from the acceleration of collagen synthesis to the scavenging of oxygen-containing radicals caused by exposure to damaging ultraviolet radiation. See '693 patent, col. 5, ll. 30-

35, col. 6, ll. 35-50; '063 patent, col. 6, ll. [*4] 3-15, col. 7, ll. 30-45.

In 1999, Dr. Perriconè sued Medicis, alleging that Medicis infringed both the '693 and '063 patents with its LUSTRAA (R) line of prescription skin depigmenters. Perricone, 267 F. Supp. 2d at 232-33. LUSTRAA (R) is a cream that, with hydroquinone as its active ingredient, reduces the production of melanin, i.e., the pigment in skin. LUSTRAA (R) also includes, inter alia, ascorbyl palmitate. Before the district court, Dr. Perricone filed motions for summary judgment of validity and infringement, and Medicis filed a motion for partial summary judgment of invalidity of claims 9, 11-13, 16, 18, and 19 of the '063 patent on the basis of double patenting, and of claims 1-19 of the '063 patent and claims 1-4, 7-9, and 13 of the '693 patent on the basis of anticipation. Id. at 233. Medicis also filed motions for partial summary judgment of non-infringement, premised on the invalidity of Dr. Perricone's asserted claims, and for attorney fees under 35 U.S.C. § 285. Aside from the rejected attorney fees request, the district court granted Medicis' motions and denied Dr. Perricone's. Id. at 249. [*5]

The district court's opinion and the parties' briefs before this court do not disclose the disposition of each claim of the '693 and '063 patents. The district court's opinion appears to invalidate all of the asserted claims of both patents, yet grants summary judgment of non-infringement only for the '693 patent. See id. Dr. Perricone's opening brief suggests that the district court's non-infringement ruling applies to the asserted claims of both patents. Dr. Perricone's opening brief at 1. Nevertheless, this court need not determine the correct status of each claim. Rather, this court confines its rulings to reversal of a clearly identifiable subset of the '693 claims and trusts the parties to resolve any uncertainty on remand.

II.

This court reviews a district court's grant of summary judgment without deference and a denial of summary judgment for an abuse of discretion, Electromotive Div. of Gen. Motors Corp. v. Transp. Sys. Div. of Gen. Elec. Co., 417 F.3d 1203, 1209 (Fed. Cir. 2005), drawing all reasonable inferences in favor of the nonmovant. This court gives due weight to a patent's presumed validity under 35 U.S.C. § 282 (2000), [*6] requiring an accused infringer to prove invalidity by clear and convincing evidence. Geneva Pharm., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1377 (Fed. Cir. 2003). This court reviews double patenting without deference. Georgia-Pacific Corp. v. U.S. Gypsum Co., 195 F.3d 1322, 1326 (Fed. Cir. 1999).

Double Patenting

The double patenting doctrine generally prevents a patentee from receiving two patents for the same invention. Thus, this doctrine polices the proper application of the patent term for each invention. The proscription against double patenting takes two forms: statutory and non-statutory. Statutory, or "same invention," double patenting is based on the language in § 101 of the Patent Act mandating "a patent" for any new and useful invention. 35 U.S.C. § 101 (2000); In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) ("If the claimed inventions are identical in scope, the proper rejection is under 35 U.S.C. § 101 because an inventor is entitled to a single patent for an invention.") (citations omitted). Non-statutory, or "obviousness-type," double patenting is a judicially [*7] created doctrine adopted to prevent claims in separate applications or patents that do not recite the "same" invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection. Gerber Garment Tech., Inc. v. Lectra Sys., Inc., 916 F.2d 683, 686 (Fed. Cir. 1990) (citing In re Thorington, 57 C.C.P.A. 759, 418 F.2d 528, 534 (CCPA 1969)). This case involves double patenting in this latter category.

Claim 1 of the '693 patent recites:

> 1. A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-richlayers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.

'693 patent, col. 7. Meanwhile, claim 9 of the '063 patent recites:

> 9. A method for the treatment of skin damaged or aged by oxygen-containing free radicals or oxidative generation of biologically active metabolites which comprises topically applying to affected skin areas a composition [*8] containing an effective amount of an ascorbyl fatty acid ester in a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin.

'063 patent, cols. 8-9. The district court found claim 9 of the '063 patent invalid under the non-statutory double patenting doctrine in view of claim 1 of the '693 patent. In reaching that conclusion, the district court first identified differences between the two claims:

> (1) claim 9 of the '063 patent teaches a method for treatment of certain skin disorders, while claim 1 of the '693 patent teaches a method for treatment of sunburn; (2) claim 9 of the '063 patent recites the use of "an effective amount of an ascorbyl fatty acid ester . . . ," while claim 1 of the '693 patent teaches applying an ascorbyl fatty acid ester "effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge free radicals present as a result of the transfer of energy to the skin from the ultraviolet radiation which produced the sunburn"; and (3) claim 9 of the '063 patent recites the use of "a dermatologically acceptable, fat-penetrating carrier such that the [*9] ester is percutaneously delivered to lipid-rich layers of the skin," while the '693 patent does not explicitly recite the use of a carrier.

Perricone, 267 F. Supp. 2d at 240. The district court analyzed those distinctions. In the first place, the district court noted that "sunburn is a species of the genus of skin disorders" covered by the '063 patent. Id. Next, consulting the specifications of both patents, the district court concluded that the claimed effective amount in the '063 patent falls within the ranges of effective amounts in the '693 patent. Finally, the district court construed the "effective to solubilize" language in claim 1 of the '693 patent to mean the same thing as the language in claim 9 of the '063 patent requiring "a dermatologically acceptable, fat-penetrating carrier such that the ester is percutaneously delivered to lipid-rich layers of the skin." Accordingly, the district court found claim 9 of the '063 patent invalid for obviousness-type double patenting in view of claim 1 of the '693 patent.

Claims 11-13 of the '063 patent all depend from independent claim 9. Thus, the district court's analysis of claim 9 applies equally to claims [*10] 11-13. Claim 11 includes an additional limitation specifying a particular range of concentration of the ester. Because that range substantially overlaps the range in claim 5 of the '693 patent (dependent on claim 1 of the '693 patent), the district court determined that claim 11 of the '063 patent is also obvious in view of claim 5 of the '693 patent. Id. at 242. For claims 12 and 13 of the '063 patent, the district court determined that those claims added the same limitations to independent claim 9 as claims 3 and 4 added to claim 1 of the '693 patent. Thus, the district court determined that dependent claims 11-13 fall with claim 9 of the '063 patent for the above reasons. Id. at 241.

Independent claim 16 of the '063 patent includes limitations analogous to those in independent claim 9. Accordingly, the district court applied the same reasoning for its double patenting determination of claim 16. Id. at 241-42. The district court paid special attention to the additional recitation in claim 16 of specific "tocotrienols," but determined that those tocotrienols are not patentably distinct from the Vitamin E of claim 7 of the '693 patent. [*11] Finally, the district court determined that claims 18 and 19 of the '063 patent, which both depend from claim 16 of that patent, are not patentably distinct from claims 4 and 7.

This court first examines the contention that the claims of the '063 patent contain "material differences" from those in the '693 patent. This "material differences" argument does not show that the district court erred in its double patenting analysis. Rather, the district court's analysis specifically addresses differences between the claims of the '693 and '063 patents. For instance, the district court discussed the difference between the recitation in the '063 patent's claim 9 of "a dermatologically acceptable fat-penetrating carrier" and claim 1's recitation of no carrier at all. Thus, the district court cogently reasoned that, based on the specification, the "effective to solubilize" language in claim 1 of the '693 patent means the same thing as the "carrier" language in claim 9. Thus, the difference disappears.

Likewise, the district court properly resolved the apparent difference between treatment of various types of skin damage in claims 9 and 16 of the '063 patent and treatment of sunburn in claim [*12] 1. Sunburn is a species of skin damage. As such, this court perceives no error in the district court's determination that the earlier species renders the later genus claims invalid under nonstatutory double patenting. See Eli Lilly & Co. v. Barr Labs., Inc. 251 F.3d 955, 971 (Fed. Cir. 2001) ("[This court's] case law firmly establishes that a later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim.") (citations omitted).

Finally, the district court did not misconstrue the genus-species relationship between claim 16 of the '063 patent and claim 7 of the '693 patent. The district court interpreted the language of claim 16 reciting various tocotrienols, and concluded that it "refers to certain forms of tocopherols, or Vitamin E." Perricone, 267 F. Supp. 2d at 238. Thus, the district court did not improperly conclude that a species was obvious in light of an earlier claim to a genus but correctly concluded that there was no patentable distinction between the language of claim

16 of the '063 patent and claim 7 of the '693 patent. This court finds no error in that analysis.

The district court [*13] also considered and correctly rejected the suggestion that procedures of the United States Patent and Trademark Office (PTO) militate against double patenting. Specifically, if Dr. Perricone had presented all the claims of the '693 and '063 patents to the PTO in a single application, the PTO might have made a restriction requirement. In other words, the PTO might have separated the claimed subject matter into different classifications and different inventions. If the PTO had entered a restriction requirement under that hypothetical situation, 35 U.S.C. § 121 would have barred a double patenting rejection. Yes, and if the court had a brother, he might like buttermilk. In other words, this tortured hypothetical does not correspond to the record in this case. The various claims were not filed together nor restricted by the PTO. Thus, in simple terms, 35 U.S.C. § 121 does not rescue Dr. Perricone's voluntarily filed continuation-in-part application.

Finally, and contrary to the suggestion by the district court, the Patent Act and PTO rules support the filing of a terminal disclaimer even after issuance of the second patent. See 35 U.S.C. § 253 [*14] (2000) ("Any patentee. . . may disclaim or dedicate to the public the entire term, or any terminal part of the term, of the patent granted . . . ."); 37 CFR § 1.321(a) (incorporating the language of § 253). The district court's focus on In re Goodman, 11 F.3d 1046, 1052 (Fed. Cir. 1993) (explaining that a terminal disclaimer can overcome a double patenting "rejection") seems to have led to its conclusion that a terminal disclaimer cannot be filed for an issued patent to overcome invalidity based on double patenting. The commentary from In re Goodman arose in the context of ex parte prosecution, a setting not applicable to this case. An applicant must always overcome every rejection to gain issuance of a patent. Accordingly, the pre-issuance timing requirement of a terminal disclaimer to overcome a double patenting rejection does not dictate a prohibition on post-issuance terminal disclaimers. A terminal disclaimer can indeed supplant a finding of invalidity for double patenting. See Applied Materials, Inv. v. Semiconductor Materials Am., Inc., 98 F.3d 1563, 1577 (Fed. Cir. 1996) ("For obviousness-type double patenting, [*15] [the improper extension of the statutory term] problem can sometimes be avoided for co-owned patents. . . through the use of a terminal disclaimer."). This record, however, does not include any evidence of a disclaimer even though the district court invalidated the claims over two years ago. Thus, while Dr. Perricone might still file a terminal disclaimer to overcome prospectively the double patenting basis for invalidity, this court makes no determination about the retrospective effect of such a terminal disclaimer.

Anticipation

A single prior art reference that discloses, either expressly or inherently, each limitation of a claim invalidates that claim by anticipation. Minn. Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1565 (Fed. Cir. 1992). Thus, a prior art reference without express reference to a claim limitation may nonetheless anticipate by inherency. See In re Cruciferous Sprout Litig., 301 F.3d 1343, 1349 (Fed. Cir. 2002). "Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claims limitations, it anticipates." Id. (quoting MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1365 (Fed. Cir. 1999). [*16] Moreover, "ihherency is not necessarily coterminous with knowledge of those of ordinary skill in the art. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art." Id.; see also Schering Corp. v. Geneva Pharms., 339 F.3d 1373, 1377 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition in the prior art) (citing In re Cruciferous Sprout Litig., 301 F.3d at 1351; MEHL/Biophile, 192 F.3d at 1366).

The district court determined that U.S. Patent No. 4,981,845 (Pereira) anticipates claims 1-4, 7-9, and 13 of the '693 patent, and claims 1-19 of the '063 patent. Perricone, 267 F. Supp. at 243. Pereira teaches a cosmetic composition for topical application and discloses various ingredients in that composition, including skin benefit ingredients, emollients, emulsifiers, and thickeners. See Pereira, cols. 1-2. In addition to listing examples, Pereira discloses eight distinct example compositions with specific concentrations of ingredients. Id. at cols. 8-12. Pereira identifies the disclosed compositions only briefly, identifying [*17] them as "suitable for topical application to the skin or hair." Pereira, col. 1, ll. 6-8. The district court concluded that Pereira's disclosed use anticipates Dr. Perricone's claims because Pereira's disclosed compositions include all the various ingredients in the concentrations claimed by Dr. Perricone. Thus, according to the district court, the topical application of Pereira's compositions would necessarily yield Dr. Perricone's claimed skin benefits. On appeal, Dr. Perricone argues that: (1) Pereira's disclosed skin benefit ingredients include ascorbyl palmitate among many others, and so Pereira's disclosure does not anticipate the specific claimed use of ascorbyl palmitate; (2) Pereira's disclosed range of concentration of its skin benefit ingredient only partially overlaps with Dr. Perricone's claimed range; and (3) Pereira does not disclose any benefit directed to skin sunburn, or any of the other specific skin disorders, as claimed by Dr. Perricone.

With respect to its skin benefit ingredient, Pereira discloses "from 0.01 to 20% by weight of a skin benefit

ingredient chosen from: . . . Ascorbyl palmitate and Tocopherol [i.e., Vitamin E] . . . ." Pereira, col. 1, ll. 55-68. In [*18] addition to those two identified ingredients, Pereira lists an additional twelve ingredients. See id. In total, Pereira teaches a total of fourteen skin benefit ingredients. This court rejects the notion that one of these ingredients cannot anticipate because it appears without special emphasis in a longer list. To the contrary, the disclosure is prior art to the extent of its enabling disclosure. See Hewlett-Packard Co. v. Mustek Sys., Inc., 340 F.3d 1314, 1324 n.6 (Fed. Cir. 2003) ("The anticipation analysis asks solely whether the prior art reference discloses and enables the claimed invention, and not how the prior art characterizes that disclosure or whether alternatives are also disclosed.") (citing Celeritas Techs. v. Rockwell Int'l Corp., 150 F.3d 1354, 1361 (Fed. Cir. 1998)).

In re Baird, 16 F.3d 380, 383 (Fed. Cir. 1994), is not inconsistent with this anticipation analysis. In the first place, In re Baird involved obviousness, not anticipation. Baird observes that "disclosure of millions of compounds does not render obvious a claim to three compounds." 16 F.3d at 383 (emphasis added). [*19] Baird's reasoning, relevant to obviousness, does not apply to Pereira's disclosure of a handful of different compositions, the use of one of which anticipates Dr. Perricone's claims.

While other opinions state that disclosure of a broad genus does not necessarily specifically disclose a species within that genus, see, e.g., Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1262 (Fed. Cir. 1989), this axiomatic proposition also does not rescue Dr. Perricone's claims. In this case, the prior art does not merely disclose a genus of skin benefit ingredients without disclosing the particular claimed ingredient. Rather Pereira specifically discloses ascorbyl palmitate. That specific disclosure, even in a list, makes this case different from cases involving disclosure of a broad genus without reference to the potentially anticipating species. Thus, these cases do not alter the district court's correct anticipation reasoning.

Pereira's disclosed range of concentration also does not exactly correspond to Dr. Perricone's claimed range. Pereira's disclosure nonetheless discloses and anticipates Dr. Perricone's particular claimed "effective amount" [*20] ranges. Dr. Perricone's claims recite a number of different ranges associated with the fatty acid ester. Those claimed ranges vary in breadth from an "effective" amount in claim 1 to particular specific ranges in other claims (e.g., "up to 10% by weight," '063 patent, claim 2; "from about 0.025% to about 5% by weight," '063 patent, claim 3; "from about 0.025% to about 10% by weight," '063 patent, claim 22). Pereira discloses a range of concentration "from 0.01 to 20% by weight." Pereira, col. 1, ll. 55-68. As the district court correctly noted, Pereira's range entirely encompasses, and does not significantly deviate from, Dr. Perricone's claimed ranges. Thus, this court sustains the district court's reading of Pereira's effective amount disclosure. See Atlas Powder Co. v. IRECO Inc., 190 F.3d 1342, 1346 (Fed. Cir. 1999) ("When a patent claims a chemical composition in terms of ranges of elements, any single prior art reference that falls within each of the ranges anticipates the claim.") (citing Titanium Metals Corp. v. Banner, 778 F.2d 775, 781 (Fed. Cir. 1985)).

With respect to the particular claimed skin benefits, the district court [*21] reasoned that "Pereira will inherently function in [the claimed beneficial manner]when topically applied to the skin." Perricone, 267 F. Supp. 2d at 248. Thus, the district court ultimately based its anticipation analysis on inherency. "In general, a limitation or the entire invention is inherent and in the public domain if it is the 'natural result flowing from' the explicit disclosure of the prior art." Schering, 339 F.3d at 1379 (citing Eli Lilly &Co. v. Barr Labs., Inc., 251 F.3d 955, 970 (Fed. Cir. 2001); In re Kratz, 592 F.2d 1169, 1174 (CCPA 1979)). In some cases, the inherent property corresponds to a claimed new benefit or characteristic of an invention otherwise in the prior art. In those cases, the new realization alone does not render the old invention patentable. See Atlas Powder, 190 F.3d at 1347 ("The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's function, does not render the old composition patentably new to the discoverer."); Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001) [*22] (explaining that newly discovered results of known processes are not patentable because those results are inherent in the known processes). Thus, when considering a prior art method, the anticipation doctrine examines the natural and inherent results in that method without regard to the full recognition of those benefits or characteristics within the art field at the time of the prior art disclosure.

Dr. Perricone's five asserted independent claims recite:

> [Claim 1, '693 patent] A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid . . . .
>
> [Claim 8, '693 patent] A method for preventing sunburn damage to exposed skin surfaces, comprising topically applying to said skin surfaces . . . .
>
> [Claim 1, '063 patent] A method for the treatment of skin disorders which arise because of depleted or inhibited collagen

> synthesis which comprises topically applying to affected skin areas . . . .
>
> [Claim 9, '063 patent] A method for the treatment of skin damaged or aged by . . . which comprises topically applying to affected skin areas a composition containing . . . .
>
> [Claim 16, '063 patent] A method for the treatment [*23] of damaged or aging skin and epithelial tissue disorders. . . said treatment comprising topically applying to affected tissue areas the combination of . . . .

Thus, Dr. Perricone's independent claims recite particular skin benefits together with methods of achieving those benefits (i.e., topically applying a particular compound). * If Pereira discloses the very same methods, then the particular benefits must naturally flow from those methods even if not recognized as benefits at the time of Pereira's disclosure. Thus, Pereira anticipates if its disclosure of "topical application" satisfies the application step in Dr. Perricone's various asserted claims.

> * This court notes that while the various claimed beneficial uses appear to be recited in the preambles of Dr. Perricone's claims, the district court construed those claims as being limited by their preambles, see Perricone, 267 F. Supp. 2d at 237 (determining the scope of various preamble terms), and neither party seems to have challenged that construction. This court agrees that the district court's construction was correct.

Claim 1 of the '693 patent, from which claims 2-4 and 7 ultimately [*24] depend, specifically recites application of the fatty acid ester to "skin sunburn." This claim term raises a different problem. The issue is not, as the dissent and district court imply, whether Pereira's lotion if applied to skin sunburn would inherently treat that damage, but whether Pereira discloses the application of its composition to skin sunburn. It does not. This court explained in Catalina Marketing International, Inc. v. Cool Savings.com, Inc. that a patent to an apparatus does not necessarily prevent a subsequent inventor from obtaining a patent on a new method of using the apparatus. 289 F.3d 801, 809 (Fed. Cir. 2002). New uses of old products or processes are indeed patentable subject matter. See 35 U.S.C. § 101 (2000) (identifying as patentable "any new and useful improvements" of a process, machine, manufacture, etc.); In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986) (principles of inherency do not prohibit a process patent for a new use of an old structure). That principle governs in this case as well.

Claim 1 of the '693 patent recites a new use of the composition disclosed by Pereira, i.e., the [*25] treatment of skin sunburn. The district court's inherent anticipation analysis for this claim contains a flaw. The disclosed use of Pereira's lotion, i.e., topical application, does not suggest application of Pereira's lotion to skin sunburn. In other words, the district court's inherency analysis goes astray because it assumes what Pereira neither disclosed nor rendered inherent. Because Pereira does not disclose topical application to skin sunburn, this court reverses the district court's holding that Pereira anticipates claims 1-4 and 7 of the '693 patent.

Like the district court, the dissent seems to ignore, or at least dismiss as "not substantial[]," the distinction between Dr. Perricone's claimed method and Pereira's disclosed method. Thus, the dissent characterizes both methods the same way: "Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin." Unfortunately, the dissent can make that statement only by dismissing the explicit language of Dr. Perricone's claimed method: "applying to the skin sunburn. [*26] " '693 patent, claim 1. Skin sunburn is not analogous to skin surfaces generally. Thus, there is an important distinction between topical application to skin for the purpose of avoiding sunburn, and the much narrower topical application to skin sunburn. That distinction highlights the flaw in the dissent's knee brace hypothetical, which suggests that a particular prevention method necessarily anticipates a treatment method. To use a more apt analogy, the disclosure that a sunburn can be prevented by wearing a hat clearly does not anticipate a claim to the discovery that one can treat an existing sunburn by putting on a hat. The dissent attempts to bolster its analogy by comparing the mechanism underlying its knee brace analogy to Dr. Perricone's invention. With that comparison, the dissent drifts even farther from the facts of this case. The alleged anticipating reference here is Pereira, not Dr. Perricone's own teachings. Pereira is silent about any sunburn prevention or treatment benefits, not to mention the mechanisms underlying such uses. If Pereira did teach sunburn prevention, as well as the mechanism behind that prevention, those teachings might suggest that Dr. Perricone's sunburn [*27] treatment claims would have been obvious. However, those unrealized possibilities do not alter the analysis in this case where Pereira does not disclose topical application to skin sunburn.

Unlike claim 1, claim 8 of the '693 patent, from which claims 9 and 13 ultimately depend, merely requires application of the composition to exposed skin

surfaces. Because all skin surfaces are susceptible to sunburn damage, and because one can only realistically apply a composition to a skin surface when that surface is exposed, Pereira's "topical application" encompasses the application step of claim 8. Thus, the district court correctly determined that Pereira's disclosure of the topical application of the same composition necessarily anticipates claims 8, 9, and 13 of the '693 patent.

Claim 1 of the '063 patent, from which claims 2-8 of that patent ultimately depend, recites application to "affected skin areas." That claim further recites that those skin areas suffer from "depleted or inhibited collagen synthesis." '063 patent, claim 1. The specification of the '063 patent, meanwhile, explains that such damage results from, inter alia, "the natural aging process." '063 patent, col. 1, ll. [*28] 46-50. Because all skin is a victim of that process, claim 1 of the '063 patent ultimately claims merely the topical application of the recited composition. Likewise, claim 9 of the '063 patent, from which claims 10-15 of that patent ultimately depend, recites application of the composition to "affected skin areas" where those areas are further identified as being "aged." As such, because all skin ages, the application step of claim 9 merely requires application of the composition to skin. Similarly, the "affected tissue areas" of claim 16 of the '063 patent, from which claims 17-25 ultimately depend, are identified in that claim as "aging skin." Thus, as with claims 1 and 9 of the '063 patent, claim 16 claims merely the topical application of the recited composition. Because Pereira discloses the very same composition and teaches its topical application, the district court correctly applied the inherency doctrine. Using the same composition claimed by Dr. Perricone in the same manner claimed by Dr. Perricone naturally results in the same claimed skin benefits.

In an effort to support the district court's invalidity ruling on other grounds, Medicis has directed this court's attention [*29] to a number of other references that Medicis argues anticipates Dr. Perricone's claims. This court declines to consider grounds for invalidity not relied on by, and not appealed from, the district court.

Infringement

Recognizing that invalidity is an affirmative defense to infringement, the district court granted Medicis' motion for summary judgment of non-infringement of the '693 patent. Perricone, 267 F. Supp. 2d at 248-49. The district court likewise denied Dr. Perricone's motion for summary judgment of infringement. Because it reverses the district court's grant of summary judgment on claims 1-4 and 7 of the '693 patent, this court also vacates the district court's summary judgment of non-infringement on those claims.

Attorney Fees

In the cross-appeal, Medicis challenges the districtcourt's denial of its motion for attorney fees under § 285. Medicis asks this court either to remand on the exceptional case question or to "declare the case exceptional without further proceedings." Medicis' opening brief at 64. This court declines that invitation.

An award of attorney fees under 35 U.S.C. § 285 involves a two-part determination. [*30] First, a district court must determine whether the prevailing party has proven an exceptional case by clear and convincing evidence. Forest Labs., Inc. v. Abbott Labs., 339 F.3d 1324, 1327 (Fed. Cir. 2003) (citing Ruiz v. A.B. Chance Co., 234 F.3d 654, 669 (Fed. Cir. 2000)). This court reviews an exceptional case finding for clear error. Id. at 1328. Second, if the district court finds the case exceptional, it must then determine whether an award of attorney fees is appropriate. Id. This court reviews that determination for an abuse of discretion. Id. (citing Cybor Corp. v. FAS Techs., 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc)). As this court explained in Frank's Casing Crew v. Weatherford International, trial judges enjoy discretion to award attorney fees for good reason. 389 F.3d 1370, 1379 (Fed. Cir. 2004). "After presiding over the preparation and trial of the case, the trial judge can best weigh the relevant considerations, such as the closeness of the case, the tactics of counsel, the flagrant or good faith character of the parties' conduct, and any other factors contributing to imposition [*31] of punitive sanctions or to fair allocation of the burdens of litigation." Id. (citing Modine Mfg. Co. v. Allen Group Inc., 917 F.2d 538, 543 (Fed. Cir. 1990); S.C. Johnson & Son, Inc. v. Carter-Wallace, Inc., 781 F.2d 198, 201 (Fed. Cir. 1986)). This case exhibits those considerations.

Medicis' arguments appear to focus on the timing and content of various expert reports proffered by Dr. Perricone, the propriety of various responses by Dr. Perricone to Medicis' requests for admissions, and demands made by Dr. Perricone during settlement negotiations. While the timing and content of some of those documents might be questionable, Medicis points to nothing establishing that the district court committed clear error regarding whether this case is exceptional. Moreover, even if this court determined that this case should have been declared exceptional, the district court's failure to award attorney fees would not rise to an abuse of discretion given that court's familiarity with the various relevant details of Dr. Perricone's conduct in this case.

CONCLUSION

This court affirms the district court's summary judgment of invalidity of claims 1-19 of [*32] the '063 patent and claims 8, 9, and 13 of the '693 patent. However, because the district erred in its anticipation analysis of claims 1-4 and 7 of the '693 patent, this court reverses

the district court's summary judgment of invalidity as to those claims. Moreover, this court vacates the district court's summary judgment of non-infringement of claims 1-4 and 7 of the '693 patent, but affirms that summary judgment as to the remaining claims in that patent. Finally, this court affirms the district court's denials of Medicis' motion for attorney fees under 35 U.S.C. § 285. This court remands for further proceedings.

COSTS

Each party shall bear its own costs.

AFFIRMED-IN-PART, REVERSED-IN-PART, VACATED-IN-PART and REMANDED

CONCURBY: BRYSON (In Part)

DISSENTBY: BRYSON (In Part)

DISSENT: BRYSON, Circuit Judge, concurring in part and dissenting in part.

I concur in most aspects of the court's opinion, including the portions upholding the district court's ruling that claims 1-19 of the "skin disorder" patent, U.S. Patent No. 5,574,063, and claims 8, 9, and 13 of the "sunburn" patent, U.S. Patent No. 5,409,693, are anticipated by U.S. Patent No. 4,981,845 ("the Pereira [*33] patent"). I dissent, however, from the portion of the judgment holding that the Pereira patent does not anticipate claims 1-4 and 7 of the sunburn patent. In my view, the differences between the claims that the court invalidates and those that it holds not to be invalid do not justify a difference in outcome. The written description of the sunburn patent is identical to the pertinent portions of the written description of the skin disorder patent in all material respects. The only significant difference between the two patents for present purposes is that the sunburn patent claims methods for treating and preventing sunburn comprising the topical application of the composition described in the specification, while the skin disorder patent claims a method for treating skin disorders comprising the topical application of the same composition. Moreover, the only difference between the claims of the sunburn patent that this court invalidates and those that it upholds is that the former recite methods for preventing sunburn while the latter recite methods for treating sunburn. The differences between the sunburn and the skin disorder patents, and among the claims of the sunburn patent, [*34] simply highlight inherent features of the compositions that are disclosed both in the common written description of the two patents in suit and in the Pereira patent. Under our precedents, those differences do not suffice to avoid anticipation.

Claim 1 of the sunburn patent recites:

> A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn.

Dependent claims 2-4 and 7 recite a method for treating skin sunburn in which the fatty acid ester of ascorbic acid is topically applied to the skin in the form of a composition including a dermatologically acceptable carrier (claim 2), in which the fatty acid ester of ascorbic acid is selected from a group including ascorbyl palmitate (claim 3), in which the fatty acid ester of ascorbic acid is ascorbyl palmitate (claim 4), and in which the composition includes Vitamin E (claim 7). Independent claim 8 and dependent claims 9 and 13 are similar to claims [*35] 1, 2, and 7, except that they recite a method for preventing sunburn damage to exposed skin.

In explaining the effectiveness of the claimed method, the sunburn patent states:

> The effectiveness of the ascorbyl fatty acid esters in the treatment of . . . radiation-induced skin damage . . . can be postulated as resulting from the antioxidant properties of ascorbic acid per se, which properties are retained to a high degree in the ascorbyl fatty acid ester form, together with the fact that the ascorbyl fatty acid ester form is capable of being delivered in an effective manner.

Sunburn patent, col. 6, ll. 35-43. The patent further explains that "when solubilized in the lipid-rich layers of the skin, the fatty acid ester form of ascorbic acid is capable of scavenging free oxygen-containing radicals, neutralizing other reactive oxidants released extracellularly and intracellularly, and either interfering with or minimizing oxidative generation of metabolites . . . ." Id. col. 6, ll. 43-47. The patent describes the invention as one

> which involves the topical application of fat-soluble fatty acid esters of ascorbic acid . . . . By virtue of the fat-solubility of [*36] these fatty acid esters and the further enhancement of this solubility via admixture with fat-penetrating carriers, the active ascorbic acid can be effectively percutaneously delivered to lipid layers so

as to bring about these effects and actions

. . . .

Id. col. 6, ll. 50-63.

The Pereira patent discloses a composition containing each of the components recited in the sunburn patent, and in amounts falling within the same range. In addition, the Pereira patent discloses that the emulsion of the invention comprises "a selected skin benefit ingredient, a special emulsifier and an emollient oil," which is effective for delivering the skin benefit agent "to subcutaneous regions of the skin." Pereira patent, col. 1, ll. 14-15; id. col. 2, ll. 13-14. Among the skin benefit ingredients listed in the Pereira patent is ascorbyl palmitate. Pereira further discloses a number of substances for use as the emollient ingredient, including lethicin. Id. col. 4, ll. 67-68.

The evidence before the district court established that the Pereira patent discloses topical application of the same substance that is claimed in the sunburn patent, with the same results. Thus, the evidence [*37] showed that certain of the skin benefit ingredients of Pereira, including ascorbyl palmitate, operate to benefit the skin by scavenging free radicals. In addition, the evidence showed that lecithin is a dermatologically acceptable carrier that is able to "solubilize the lipid-rich layers of the skin," as required by the sunburn patent. And the concentration levels of the skin benefit ingredients of Pereira encompass the levels that the sunburn patent asserts are effective in treating and preventing sunburn.

To be sure, Pereira does not expressly refer to the use of the disclosed composition to treat or prevent sunburn. As the district court noted, however, those benefits are inherent in the topical application of the composition claimed in Pereira. The fact that Pereira does not assert that the emulsion is effective in preventing or treating sunburned skin does not avoid anticipation of the sunburn patent, as long as those benefits are the natural result of the normal use of the Pereira emulsion. See MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999) (prior art article anticipates because it describes a process that necessarily performs [*38] the claimed process; "where . . . the result is a necessary consequence of what was deliberately intended, it is of no consequence that the article's authors did not appreciate the results"); Atlas Powder Co. v. Ireco, 190 F.3d 1342, 1347 (Fed. Cir. 1999) ("Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates."); In re King, 801 F.2d 1324, 1326 (Fed. Cir. 1986), quoting In re Ackenbach, 18 C.C.P.A. 769, 45 F.2d 437, 439, 1931 Dec. Comm'r Pat. 84 (CCPA 1930) ("if a previously patented device, in its normal and usual operation, will perform the function which an appellant claims in a subsequent application for process patent, then such application for process patent will be considered to have been anticipated by the former patented device"). Although Dr. Perricone may have discovered that among the skin benefits of the composition disclosed by Pereira are the prevention and treatment of sunburn, the discovery of a new property of the Pereira composition, when used in accordance with its normal application, is not a sufficient basis for avoiding anticipation. See In [*39] re Cruciferous Sprout Litig., 301 F.3d 1343, 1350-51 (Fed. Cir. 2002) ("Brassica has done nothing more than recognize properties inherent in certain prior art sprouts . . . . While Brassica may have recognized something quite interesting about those sprouts, it simply has not invented anything new."); EMI Group, N. Am., Inc. v. Cypress Semiconductor Corp., 268 F.3d 1342, 1349 (Fed. Cir. 2001) ("The discovery of a previously unappreciated property of a prior art composition . . . does not render the old composition patentably new to the discoverer."); Atlas Powder, 190 F.3d at 1349 ("discovery of an inherent property of the prior art [does] not [constitute] the addition of a novel element" and therefore does not serve as patentable subject matter).

This is not a case in which the patentee is claiming a method that consists of a new way of using a previously known product in order to achieve a new result. The Supreme Court long ago explained that "if an old device or process be put to a new use which is not analogous to the old one, and the adaptation of such process to the new use is of such a character as to require the [*40] exercise of inventive skill to produce it, such new use will not be denied the merit of patentability." Ansonia Brass & Copper Co. v. Elec. Supply Co., 144 U.S. 11, 18, 12 S. Ct. 601, 36 L. Ed. 327, 1892 Dec. Comm'r Pat. 313 (1892). Importantly, however, the Court qualified that rule by adding that "the application of an old process or machine to a similar or analogous subject, with no change in the manner of application and no result substantially distinct in its nature, will not sustain a patent even if the new form of result had not before been contemplated." Id.; see also Brown v. Piper, 91 U.S. 37, 41, 23 L. Ed. 200, 1876 Dec. Comm'r Pat. 464 (1875) (prior art patent for a "corpse preserver" anticipated method for preserving fish and meats that used the same steps; Court held that the new method "was simply the application by the patentee of an old process to a new subject . . . . The thing was within the circle of what was well known before, and belonged to the public. No one could lawfully appropriate it to himself, and exclude others from using it in any usual way for any purpose to which it may be desired to apply it.").

The majority accurately describes that governing principle of law when it states: [*41] "If Pereira discloses the very same methods, then the particular benefits must naturally flow from those methods even if not recognized as benefits at the time of Pereira's disclosure." That principle, however, leads me to a conclusion different from the one reached by the majority, at least as to the sunburn treatment claims. In my view, the method of using the composition recited in the sunburn patent is not substantially different from the "skin benefit" use described by Pereira. The prevention and treatment of sunburn therefore do not qualify as "new uses" of the composition so as to avoid anticipation. See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 809-10 (Fed. Cir. 2002) (stating, for illustration, that a claimed use of shoe polish to repel water on shoes does not constitute a "new use" of the prior art polish, although a claimed use of the shoe polish to grow hair would so qualify).

Pereira describes not only the same product that is claimed in the sunburn patent, but also the same method of using it, i.e., topically applying it to the skin in an amount necessary to have beneficial effects on the skin. Dr. Perricone's contribution is [*42] simply to recognize that among those skin benefits is the prevention and treatment of sunburn. That identification of a new subset of a previously known property is not entitled to patent protection.

While the majority applies that principle to the sunburn prevention and skin disorder claims, it does not apply the same principle to the sunburn treatment claims, even though those claims recite the same composition and process as are disclosed in Pereira and recited in Dr. Perricone's other claims. Yet, to use the majority's language, the treatment of sunburned skin is every bit as much a "particular benefit[] that must naturally flow from [Pereira's] methods" as the prevention of sunburn and the treatment of skin disorders. Under the majority's test, the sunburn treatment claims should therefore be anticipated by Pereira just as much as the sunburn prevention claims and the skin disorder treatment claims.

The majority distinguishes the prevention claims of the sunburn patent from the treatment claims of that patent by stating that because "all skin surfaces are susceptible to sunburn damage, and because one can only realistically apply a composition to a skin surface when that [*43] surface is exposed, Pereira's 'topical application' encompasses the application step of claim 8" of the sunburn patent. But precisely the same reasoning applies to the sunburn treatment claims. The majority seems to attach significance to the notion that topical application of Pereira's emulsion always prevents sunburn, because all skin is subject to sunburn, but that it does not always treat sunburn, because not all skin is sunburned and in need of treatment. That distinction, however, does not stand up: the fact that the sunburn treatment function is pertinent to only a subset of users of the Pereira method (i.e., those already suffering from sunburn) does not mean that Pereira does not anticipate the treatment claims.

Topical application of the Pereira emulsion results in scavenging oxygen-containing free radicals and neutralizing reactive oxidants, whether the skin is sunburned or not. Thus, the effect that underlies both the prevention and treatmentof sunburn is present in all cases of topical application of the Pereira composition. For that reason, Pereira anticipates not only the skin disorder and sunburn prevention claims, but also the sunburn treatment claims, which are based [*44] on the same underlying chemical processes. To illustrate the point, if it were discovered that using a particular kind of knee brace that was long worn by athletes to provide stability and thus minimize the effect of ligament injuries would also facilitate the treatment of cartilage damage and protect against further cartilage damage, that subsequent discovery would not give rise to a patentable invention. Moreover, it surely would not be the case that the use of the brace to prevent cartilage damage would be anticipated, but the use of the brace to treat cartilage damage would not, on the ground that all knees are subject to cartilage damage, but only some knees already have it.

The majority illustrates its distinction between sunburn treatment and sunburn prevention with its own analogy, arguing that the prior use of a hat to prevent sunburn would not anticipate the use of a hat to treat sunburn. Yet this analogy is inapt because a hat prevents sunburn by a mechanism, i.e., shade, that does not treat sunburn. In contrast, the mechanism by which a knee brace minimizes the effects of ligament injury, i.e., enhanced stability, is the same mechanism that facilitates treatment of cartilage [*45] damage and also prevents further cartilage damage. The same is true here, where the same chemical process treats and prevents sunburned skin.

Furthermore, the majority's distinction between the sunburn prevention claims, which the majority invalidates, and the sunburn treatment claims, which the majority upholds, is inconsistent with its invalidation of all the asserted claims of the skin disorder patent. The majority distinguishes the sunburn treatment claims by focusing on the applicability of the skin damage patent to aging skin, and suggests that "all skin is a victim of [the natural aging process]." The skin damage patent, however, addresses "[a] wide variety of skin diseases and skin conditions in which the skin has undergone some form of accelerated aging." Skin damage patent, col. 1, ll. 26-28. Like sunburn, those diseases and conditions are not found in all persons. The majority's distinction ap-

pears to rest upon its assertion that "skin sunburn is not analogous to skin surfaces generally." However, there appears to be no greater specificity in topical application to skin that is sunburned than there is in topical application to skin that is diseased or skin that has [*46] suffered from accelerated aging. Accordingly, I submit that the majority's distinction between the treatment claims and the prevention claims is not a satisfactory ground for decision in this case.

This court's decisions in Rapoport v. Dement, 254 F.3d 1053 (Fed. Cir. 2001), and MEHL/Biophile International Corp. v. Milgraum, 192 F.3d 1362 (Fed. Cir. 1999), are not at odds with the district court's conclusion in this case. Each of those cases involved a prior art method that was directed at an objective different from the objective of the claimed invention. In Rapoport, the prior art was a method for treating anxiety by administering a certain dosage of a particular drug three times a day, while the invention was a method for treating sleep apnea by administering a larger dosage of the same drug at the time of sleep. In MEHL/Biophile, the prior art was a method of using a laser to remove tattoos by aligning the laser over the pigmented skin, while the claimed invention was a method of using a laser to remove hair by aligning the laser over hair follicles. Although in each case practicing the prior art method might sometimes have the effect [*47] that was the objective of the claimed invention, the court held in each case that practicing the prior art method would not inherently have that effect. Thus, even if the prior art method for tattoo removal were used on skin having hair, it would not anticipate the claimed method in MEHL/Biophile because the prior art method did not dictate that the laser be aligned with hair follicles. And even if the prior art treatment of anxiety were used on patients suffering from sleep apnea, it would not anticipate the claimed method in Rapoport because the timing of drug administration and the dosages employed in the two treatments were different.

In this case, by contrast, topical application of the Pereira composition to normal skin inherently produces the same chemical processes that underlie the sunburn prevention claims, including scavenging free-oxygen-containing radicals and neutralizing other reactive oxidants. Topical application of the Pereira composition to sunburned skin inherently produces the same processes, which also underlie the sunburn treatmentclaims. Because the chemical processes that have the effect of treating and preventing sunburn are inherent consequences [*48] of the normal use of the Pereira composition, Pereira anticipates all the claims of the sunburn patent, just as it anticipates all the claims of the skin disorder patent.

In substance, the sunburn patent simply selects particular ingredients from among the small class of ingredients identified in Pereira and identifies specific benefits falling within the broader characterization of benefits identified in Pereira. To hold that the treatmentclaims of the sunburn patent are not anticipated by Pereira is to permit an inventor to secure patent rights to an existing invention merely upon identifying an inherent benefit of the prior art that had not previously been specifically identified, but that falls within a broader class of benefits already identified in the prior art. Because that result is contrary to the law of inherent anticipation as I understand it, I respectfully dissent from the portion of the court's judgment relating to the treatment claims of the sunburn patent.

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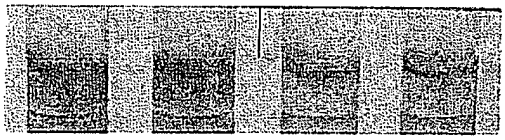
Colour range of Premi®Test-egg

Positive | Negative



Who will use Premi® Test-egg?

Premi®Test-egg is suitable for use by egg processors, retailer and by inspection laboratories. It is ideal for use "on site" as no special laboratory equipment is needed to interpret the result. The rapidly obtained "yes/no" result is simply read by colour comparison.

Test principle

Premi®Test-egg is based on the inhibition of the growth of *Bacillus stearothermophilus*, a bacterium very sensitive to many antibiotics and sulpha compounds.
A standardised number of spores is imbedded in an agar medium with selected nutrients. These spores will remain viable for many months.
When placed in the Premi®Test heating block or a waterbath at 64°C the spores will germinate.

When no antibiotics are present, the bacteria will multiply and produce acids. This will be visible by a colour change from purple to yellow. When anti microbial compounds are present at or above above the detection level, no growth will occur and the colour will remain purple.

Test procedure

Simply make a hole of approximately 1-2 cm. in the egg that needs to be tested. Prick the egg-yolk and place the egg with the hole down on a bottle. After the egg is empty, close the bottle. Then homogenise the egg by shaking the bottle. Put a sample of 0.1 ml into the test and cover the ampoule with the provided sealing. Then incubate 10 minutes at 80°C and place the test directly after that in the Premi®Test block heater or water bath with a temperature of 64°C.The test will be read after 3 hours.

Test format.

Premi®Test-egg is supplied in polystyrene boxes in quantities of 25 or 100 ampoules.

Shelf life

The test ampoules should be kept in a dark place at a constant temperature between 6 and 15 °C. The shelf-life will under these conditions is minimum 3 months.

DSM Food Specialties
Meat Ingredients
P.O. box 1, 2600 MA,Delft,
The Netherlands
tel: +31 15 2794119, fax: +31 15 2793480

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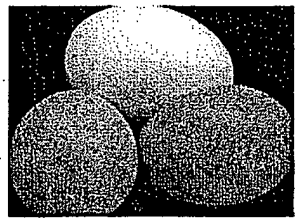
Premi®Test-egg

Broad spectrum screening test for detection of antimicrobial compounds in eggs.



Introduction

Medication of poultry administered through feed, will lead to residues in the chicken meat and in the eggs for a certain period of time.
Antibiotics are applied as medication, or as growth promotors.
Growing concerns over health related issues associated with the intake of these residues and over drug resistant bacteria have led to an increased demand for reliable test methods.
EU legislation specifies maximum residue levels for antibiotics in various products.
The Premi®Test-egg is the latest development in the microbial screening tests, which will enable you to detect the presence of antibiotic compounds in eggs.

What is Premi®Test-egg ?

Premi®Test-egg is a broad spectrum-screening test that within 3 hours detects the majority of anti-microbial compounds. It is developed based on decades of experience in the field of detection of antibiotics and sulphonamides in milk and other food products.
The test is cost effective and simple to perform.
Within 3 hours the results are available.
The test is equally suitable for testing a single sample as well as hundreds of eggs simultaneously.

Why a broad spectrum screening test?

In order to prevent that any eggs containing antibiotics enter the food chain, a fast, sensitive, reliable and easy-to-use test covering a broad range of restricted substances is needed.
Where conventional microbiological test methods generally require overnight incubation, Premi®Test-egg gives a reliable result within 3 hours. This allows you to take quick decisions on further processing of the eggs.

Premi®Test-egg is a sensitive screening test which detects a large number of antibiotics.
Unlike other tests, a negative Premi®Test-egg result reliably
indicates the absence of the most relevant antibiotics in the egg sample (see table 1).

Table 1: Sensitivity of Premi®Test-egg

Antibiotic	Limit of detection.*
B-lactams	
Penicillin	2
Amoxicillin	5
Ampicillin	4
Cloxacillin	20 – 30
Tetracyclins	
Tetracyclin	200
Oxytetracyclin	200 – 400
Doxycyclin	200
Sulfonamides	
Sulfadimidin	25 - 50
Sulfadiazin	25 - 50
Macrolides	
Tylosin	25 – 50
Erythromycin	25 - 50
Spiramycin	400
Cephalosporins	
Ceftiofur	200 – 400
Aminoglycosides	
Gentamycin	200
Streptomycin	500

* Concentration given in parts per million. (µg. /kg.)

Reading the test

A yellow colour indicates a negative sample (anti-microbial compounds below the limit of detection).

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